

USER MANUAL

1xB&D Simulation test

Vapor penetration test with test charge and indicator system class 2 according to DIN EN ISO 11140-4

Product description

The 1xB-D SIMULATION TEST is a vapor penetration test and is used in exactly the same way as the standard Bowie-Dick laundry package (see DIN EN 285). The test package contains the prescribed test load. It corresponds to the current status of European standards.

The 1xB-D SIMULATION TEST is suitable for every sterilizer and every small class B sterilizer (autoclave). It should be carried out every day before starting the activity.

The B-D test should not be confused with the vent test with a test specimen that is opened on one side. This does not meet the requirements for a Bowie-Dick test, but is only used to simulate narrow-lumen instruments or hollow bodies. The vent test is used in addition to the Bowie-Dick test.

Handling

Before you start the test, if necessary, a sterilization run (empty batch) should be carried out with the empty chamber at 134°C (see DIN EN 285 §19.2.2).

The 1xB-D SIMULATION TEST PACKAGE must be placed in the middle of the sterilizer approx. 10-20cm above the chamber floor.

Now carry out a sterilization run (Bowie Dick test program) of 134°C and a holding time of $\geqslant 3.0$ minutes with the 1xB-D.SIMULATION TEST steam penetration test. Except for this test package, the sterilizer must be empty.

After completing the run, remove the test package from the sterilizer, open the package and remove the indication sheet from the test package.

Evaluation

The Class 2 indicator must turn black clearly and evenly (see reference card). If this is not the case, repeat the test again with a new test package. If the second test does not produce the desired result, this indicates a process defect. A cause determination and risk assessment is required.

- Some causes of errors are pointed out (also refer to the reference card)
- Incorrect time and/or temperature setting
- Incorrect setting of the vacuum pump. Presence of air
- Supersaturated (moist) steam Inert gases NCG

The indicator is then stored on the documentation form or in the steri control file

with the relevant data. The indicator is self-adhesive.

The 1xB-D SIMULATION TEST does not release any toxic substances (see ISO 11140-185.9.

The 1xB-D SIMULATION TEST, with its powerful system, is intended to give you a safe and easy way to check the performance of your Steris on a daily basis, especially for parameters that cannot be tested physically (moisture and inert gases).

The indicator reacts in stages when exposed to 134 •c water vapor depending on the time from yellow to gray-brown to black. The condensation energy triggers a chemical reaction that causes the color change. Dry heat does not cause a color change. After sterilization has been completed, all fields of the indicator must be uniformly black. If this is not the case, the sterilization conditions should be critically evaluated, taking all influencing factors into account.

Notes on interpretation in the event of incomplete color change

Different yellow, brown to black fields on an indicator strip are due to insufficient vapor penetration. Causes can be, for example, a lack of vacuum performance, incorrect program, e.g. E.g. quick program, inert gases, water quality (conductivity too high), preheating temperature too low or leaks. If all indicator fields are yellow to ochre, no steam has reached the indicator. A possible cause could be a blockage in the test specimen hose. If inadequate color reactions repeatedly occur when loading and selecting the program correctly, it is recommended that the sterilizer be checked.

